

Notice of Allowability	Application No.	Applicant(s)	
	10/646,873	BILLING-MEDEL ET AL.	
	Examiner	Art Unit	
	Diana B. Johannsen	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the Interview concluding 14 March 2006.
2. ☒ The allowed claim(s) is/are 26 and 27.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| <ol style="list-style-type: none"> 1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date <u>0604</u> 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | <ol style="list-style-type: none"> 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>part of 20060306</u>. 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance 9. <input type="checkbox"/> Other _____. |
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EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Lisa V. Mueller on March 14, 2006.

2. In accordance with 37 C.F.R. 1.126, allowed claims 26-27 will be renumbered as claims 1-2, respectively (see MPEP 608.01(j)). Original claim numbers are employed in the amendment below.

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3. The application has been amended as follows:

a) Please amend the claims as follows:

In claim 26, at line 4, delete "epitope of a".

In claim 26, at line 5, delete "and fragments thereof,".

In claim 26, at line 8, after "complexes" insert "as indicative of the presence of said CS198 antigen in the test sample".

In claim 27, line 1, after "antibody" insert "or fragment thereof".

b) Please change the title of the application to:

Methods for detecting CS198 antigen.

c) Please amend the first line of the specification as follows:

The present application is a divisional of U.S. patent application serial no. 09/050,516, filed on March 30, 1998, now U.S. Patent No. 6,627,414, which is a Continuation-In-Part of abandoned U.S. patent application serial no. 08/828,855 filed on March 31, 1997, which are hereby incorporated in their entirety by reference.

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4. The following is an examiner's statement of reasons for allowance:

The closest prior art references, Hillier (GenBank Accession No. AA159525), Lamerdin (GenBank Accession No. AC004030), and Adams (Nature 377[Supp]:3-174), disclose polynucleotides comprising SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 5, SEQ ID NO: 12, SEQ ID NO: 14, and SEQ ID NO: 25. The prior art does not teach or suggest polypeptides consisting of the particular sequences set forth in the instant claims, and does not teach antibodies/antibody fragments meeting the requirements of the claims. It is also noted that the specification establishes in, e.g., Examples 10 and 14-19, that the methods of the claims are useful in the differentiation of some types of cancerous and non-cancerous tissues.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Substance of the Interview concluding March 14, 2006

5. On March 9, 2006, the examiner contacted applicant's representative Mimi C. Goller and proposed amendments to the claims that would limit them to antibodies of the type exemplified in the detection methods of the specification and place the application in condition for allowance. On March 14, 2006, applicant's representative Lisa V. Mueller contacted the examiner and agreed to the proposed amendments. Accordingly, claims 26-27 are allowed, subject to an examiner's amendment.

Drawings

6. It is noted that the drawings filed on August 22, 2003 are accepted by the examiner.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 571/272-0744. The examiner can normally be reached on Monday and Thursday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571/272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Diana B. Johannsen
Primary Examiner
Art Unit 1634

3/14/2006